11 510(k) SUMMARY

JUN 12 2006

11.0 510(k) Summary

Coapt Systems is providing a summary of the safety and effectiveness information available for the ULTRATINE TransBleph™ Device. This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92 and pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990.

SPONSOR/APPLICANT NAME AND ADDRESS

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CONTACT INFORMATION

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DATE OF PREPARATION OF 510(K) SUMMARY

January 31, 2006

DEVICE TRADE OR PROPRIETARY NAME

ULTRATINE TransBleph™ Device

DEVICE COMMON OR CLASSIFICATION NAME

Classification Name: Smooth or threaded metallic bone fixation fastener
Regulation Number: 878.3040
Class: II
Product Code: HWC

IDENTIFICATION OF THE LEGALLY MARKETED DEVICES TO WHICH EQUIVALENCE IS BEING CLAIMED

Name of Predicate Device	Product Code	Name of Manufacturer	510(k) or PMA Number
ENDOTINE TransBleph™	HWC	Coapt Systems, Inc	K040740
Vicryl	GAM	Ethicon	K944110

DEVICE DESCRIPTION

The ULTRATINE TransBleph™ consists of a bioabsorbable implant. This device is supplied sterile for single use only.

INTENDED USE STATEMENT

The ULTRATINE TransBleph™ is intended for use in subperiosteal browplasty fixation. The ULTRATINE TransBleph is specifically indicated for use to fixate the subdermis to the frontal bone.

SUBSTANTIAL EQUIVALANCE COMPARISON

1. Indications Summary

The "Indication Statement" for the ULTRATINE TransBleph™ is substantiated by the results of the performance evaluations and comparison testing to the predicate devices. The selected predicate devices are routinely used in TransBleph lift procedures. The differences between the ULTRATINE TransBleph™ and the predicate devices do not affect the safety and effectiveness of the ULTRATINE TransBleph™.

2. Technological Characteristics Summary

The ULTRATINE TransBleph™ is substantially equivalent in design, materials and fundamental scientific technology to the predicate devices. Further, the technological characteristics of the ULTRATINE TransBleph™ are similar to many absorbable, implantable general, orthopedic and plastic surgery devices legally distributed by other manufacturers. Any differences between the ULTRATINE TransBleph™ and the predicate devices are minor and do not raise issues regarding safety or effectiveness.

3. Performance Summary

The ULTRATINE TransBleph™ performance data meet the applicable standards and fulfill the device requirements as defined in the user specifications.

SUBSTANTIAL EQUIVALENCE CONCLUSION

Based on the design, materials, function, intended use, and performance evaluations discussed herein, Coapt Systems believes the ULTRATINE TransBleph™ is substantially equivalent to the predicate devices currently marketed under the Federal Food, Drug and Cosmetic Act. No new issues of safety or effectiveness were raised for

the ULTRATINE TransBleph™ Device. Therefore, safety and effectiveness are reasonably assured, justifying 510(k) clearance for commercial sale.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2006

Coapt Systems, Inc.
% Ms. Linda Ruedy
Director, Regulatory and Clinical Affairs
1820 Embarcadero Road
Palo Alto, California 94303

Re: K060248
Trade/Device Name: ULTRATINE TransBleph™
Regulation Code: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulation Class: II
Product Code: HWC
Dated: April 28, 2006
Received: April 28, 2006

Dear Ms. Ruedy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060248

Device Name: ULTRATINE TransBleph™

Indications For Use: The ULTRATINE TransBleph™ is intended for use in subperiosteal browplasty fixation. The ULTRATINE TransBleph is specifically indicated for use to fixate the subdermis to the frontal bone.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060248